K102376
p1/2

510(K) SUMMARY

- **Name and Address of Applicant**

Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, Ca 92610

Telephone: (949) 580-1555 Ext. 3325
Fax: (949) 580-1550
Attn: Steve Geerdes, Director of Regulatory Affairs

DEC - 7 2010

Date: August 12, 2010

- **Name/Trade Name of the Device:** CNS-6200 Series Central Nurse Station (i.e. CNS-6201) and Accessories

- **The common or usual Name:** Monitor, physiological, patient (with arrhythmia detection or alarms) and Telemetry Monitoring Station.

- **The Classification:** The device has been classified as Class II by the Cardiovascular Device Classification Panel under 21 CFR Part 870.1025 "Monitor, Physiological, Patient (with arrhythmia detection or alarms)" per MHX

- **The legally marketed equivalence:** The predicate device is the Nihon Kohden CNS-9701 and Accessories per 510(k) K023475 cleared on October 16, 2002.

- **A description of the device:** The device is intended for use by medical professionals to provide cardiac and vital signs monitoring for multiple patients within a medical facility. The CNS-6200 Series Central Nurse Station will display and record physiological data from up to forty telemetry receiver/transmitters and generates an alarm when a measured parameter falls outside a pre-set limit or when life threatening arrhythmia is detected. Arrhythmia detection and alarm determination are functions of the telemetry receivers/transmitters or individual bedside monitor.

- **Intended Use**
  The CNS-6200 Series Central Nurse Station is intended for cardiac and vital signs monitoring for multiple patients. The device will display and record physiological data from individual bedside monitors and /or telemetry received transmitters and mimics an alarm when a measured parameter falls outside a preset limit or when an arrhythmia is detected by the bedside monitor or telemetry unit.

  This product will be available for use by medical personnel on all patient populations within a medical facility.

- **A summary of the technological characteristics of the device compared to the predicate device:**
  - The technical characteristics of the CNS-9701A predicate and the new CNS-6200 Series are the same with the exception that the new device has new hardware such as CPU and LCD monitor

CNS-6200 Series Central Nurse Station complies with IEC 60601-1 subclause 56.3 (C) implemented by 21 CFR Part 868 Performance Standard for Electrode Lead Wires and Patient Cables.
To date, no other special controls or performance standards are known or established for this device.

The device is not sterile.

The device is not contacting patients. Therefore, no good laboratory practice studies were required per 21 CFR 58.

Design validation confirmed the operation of the software and hardware of the device is in accordance to the design specifications.

The device was subjected to electromagnetic, environmental, safety and performance testing procedures. These test verified the proper operation of the device. Design validation confirmed the operation of the software and hardware of the device is in accordance to the design specifications.

Therefore based on the above, Nihon Kohden believes that the CNS-6200 Series Central Nurse Station is substantially equivalent to the predicate device, Nihon Kohden CNS-9701A Central Nurse Station.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Nihon Kohden Corporation
c/o Mr. Steve Geerdes
Director, QA/RA
90 Icon Street
Foothill Ranch, CA 92610

DEC - 7 2010

Re: K102376
Trade/Device Name: Nihon Koden CNS-6200 Series Central Nurse Station, Model Number CNS-6201
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection and alarms)
Regulatory Class: II (two)
Product Code: MHX
Dated: November 8, 2010
Received: November 9, 2010

Dear Mr. Geerdes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102376

Indications for Use Form

510(k) Number (if known): K102376

DEC - 7 2010

Device Name: ___ CNS-6200 Series Central Nurse Station___

Indications for Use:

The CNS-6200 Series Central Nurse Station is intended for cardiac and vital signs monitoring for multiple patients. The device will display and record physiological data from individual bedside monitors and /or telemetry received transmitters and mimics an alarm when a measured parameter falls outside a preset limit or when an arrhythmia is detected by the bedside monitor or telemetry unit.

This product will be available for use by medical personnel on all patient populations within a medical facility.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102376